

Practitioner's Docket No. U 015145-3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Robert J. **MEDOFF**

Serial No.: 10/821,643

Group No. 3775

Filed: April 9, 2004

Examiner: J.L.Swiger,III

Confirmation No. 9009

For: FRACTURE FIXATION SYSTEM INCLUDING BUTTRESS PIN AND POST
WASHER

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Date of this paper: December 7, 2010

RESPONSE TO OFFICE ACTION OF AUGUST 19, 2010

In response to the Office Action of August 19, 2010 it is requested that the following amendments be made.

IN THE SPECIFICATION

Please amend paragraph [0042] as follows:

Fig. 7 diagrammatically illustrates ~~of~~ two buttress pins installed in side by side relation prior to installation of the washers and bone screws.

IN THE CLAIMS

1. (Currently Amended) ~~A fracture fixation system comprising a buttress member adapted for fracture fixation and a fixation washer for securing the buttress member to a stable bone fragment on one side of a bone fracture, said buttress member comprising a wire element having a U-shaped bend with opposite legs extending from the U-shaped bend, said legs having distal ends with portions bent away from the legs and adapted for buttressing a surface of an unstable bone fragment on an opposite side of the fracture, and including a plurality of tabs projecting from said body for engaging said legs, The combination as claimed in claim 58,~~ said fixation washer comprising a body for lying on the wire element said body having a hole for passage therethrough of a bone screw adapted to secure the washer and the underlying wire element to said stable bone fragment, and means on said body of the washer for applying a counter-bearing pressure on ~~one of the legs of the wire element in opposition to said tabs engaging said one leg~~ to oppose rotation of the washer and slippage of the washer from said legs when the bone screw is turned for engagement in the stable fragment.

2. (Cancelled)

3. (Cancelled)

4. (Currently Amended) The combination as claimed in of claim 1, ~~fracture fixation system~~ wherein said washer includes a projection extending lengthwise between the legs of the wire element, said projection having a second hole for passage therethrough of a fixation element adapted to penetrate into said unstable bone fragment.

5. (Currently Amended) The combination as claimed in claim 4, ~~fracture fixation system of~~ wherein said fixation element and the legs of said second portion ~~said bent portions at said distal ends of said legs~~ of the wire element extend at an angle relative to one another.

6. (Cancelled)

7. (Cancelled)
8. (Cancelled)
9. (Cancelled) \
10. (Cancelled)
11. (Cancelled)
12. (Cancelled)
13. (Cancelled)
14. (Cancelled)
15. (Cancelled)
16. (Cancelled)
17. (Cancelled)
18. (Cancelled)
19. (Cancelled)
20. (Cancelled)
21. (Cancelled)
22. (Cancelled)

23. (Cancelled)

24. (Cancelled)

25. (Cancelled)

26. (Cancelled)

27. (Currently Amended) The combination as claimed in claim 58, said fixation washer comprising a body for lying on the wire element ~~A fracture fixation system comprising a buttress member adapted for fracture fixation and a fixation washer for securing the buttress member to a stable bone fragment on one side of a bone fracture, said buttress member comprising a wire element having a U-shaped bend with opposite legs extending from the U-shaped bend, said legs having distal ends with portions bent away from the legs and adapted for buttressing a surface of an unstable bone fragment on an opposite side of the fracture, and including a plurality of tabs projecting from said body for engaging said legs, said body having a second hole longitudinally spaced from the first hole in a position for insertion of a fixation element adapted for being secured to the unstable bone fragment.~~

28. (Currently Amended) The combination as claimed in claim 27 ~~The fracture fixation system of claim 27~~, wherein said fixation element comprises a screw adapted for insertion into the unstable fragment of the bone.

29. (Currently Amended) The combination as claimed in claim 27 ~~The fracture fixation system of claim 27~~, wherein said fixation element comprises a post adapted for threaded engagement in the unstable fragment of the bone.

30. (Currently Amended) The combination as claimed in claim 29 ~~The fracture fixation system of claim 29~~, wherein said post has a threaded head and said second hole is threaded for threaded engagement by said threaded head of the post.

31. (Currently Amended) The combination as claimed in claim 29 ~~The fracture fixation system of claim 29~~, wherein said fixation element includes a portion adapted for buttressing the unstable bone fragment at an articulate surface thereof, said legs of said second portion ~~portions of the legs~~ being adapted for buttressing the articulate surface, said portion of the fixation element and said legs of said second portion ~~portions of the legs~~ extending at different angles with respect to the articulate surface.

32. (Currently Amended) The combination as claimed in claim 31 ~~The fracture fixation system of claim 31~~, wherein said portion of the fixation element and said legs of said second portion ~~portions~~ of the wire element extend in opposite directions of inclination.

33. (Currently Amended) The combination as claimed in claim 27 ~~The fracture fixation system of claim 27~~, wherein said second hole extends obliquely in said projection ~~body of the washer~~.

34. (Currently Amended) The combination as claimed in claim 27 ~~The fracture fixation system of claim 27~~, wherein said fixation element is secured in said body projection ~~body~~ by an expandible bearing in said second hole.

35. (Cancelled)

36. (Currently Amended) The combination as claimed in claim 27 ~~The fracture fixation system of claim 35~~, wherein the second hole causes the fixation element to be angularly offset with respect to the ~~buttressing portions of the legs~~ of the wire element.

37. (Currently Amended) The combination as claimed in claim 36 ~~The fracture fixation system of claim 36~~, wherein the angular offset of the fixation element and the ~~buttressing portions~~ legs of the second portion of the wire element are adapted to produce separate contact regions with the articulate portion of the bone fragment.

38. (Currently Amended) An implant for stabilization of an unstable bone fragment in

relation to a stable bone fragment, said implant comprising an offset buttress pin comprising a single wire element having a U-shaped bend with opposite legs extending from the U-shaped bend, said opposite legs each having a first portion that lies in a plane of the U-shaped bend and a second portion that lies in a plane outside the plane of the U-shaped bend, said ~~leg~~ legs having ~~a bend~~ respective bends integrally and continuously joining said first and second portions, said second portion being of sufficient length for bearing against and buttressing the unstable fragment, said first portion of said legs having a first region in proximity to said U-shaped bend and a second region in ~~prioximity~~ proximity to said second portion, said legs being spaced apart in said first region at a distance which is different from the spacing of the legs in said second region.

39. (Previously Presented) The implant of claim 38, wherein the legs extend parallel to one another in said first and second regions.

40. (Previously Presented) The implant of claim 39, wherein one of said legs is bent outwardly in a direction away from the other of the legs to form a step separating the first and second regions.

41. (Previously Presented) The implant of claim 38, wherein said opposite legs extending from the U-shaped bend are of equal length.

42. (Previously Presented) The implant of claim 38, wherein said opposite legs extending from the U-shaped bend are of unequal length.

43. (Previously Presented) The implant of claim 38, wherein the lengths of said wire element at said second portions of the legs are unequal.

44. (Cancelled)

45. (Currently Amended) The implant of claim 38, wherein one of said legs of the wire element is straight and the other leg has a bend therein to define first and second sections in which the legs are parallel and spaced apart and wherein the spacing between the legs in the

first ~~sections~~ section is less than the spacing between the legs in the second ~~sections~~ section.

46. (Cancelled)

47. (Cancelled)

48. (Cancelled)

49. (Cancelled)

50. (Cancelled)

51. (Cancelled)

52. (Cancelled)

53. (Cancelled)

54. (Currently Amended) The ~~fracture fixation implant system~~ of claim 2 38, wherein said wire element has a round cross-section.

55. (Cancelled)

56. (Currently Amended) The combination as claimed in claim 6 58, ~~fracture fixation system~~ of comprising a second buttress member adjacent to the first said buttressing member, said washer engaging one said leg of each of said first and second buttress members for securing said first and second buttress members to the stable bone fragment.

57. (Cancelled)

58. (Previously Presented) The implant of claim 38 in combination with a fixation washer for securing the wire element to a bone in proximity to said first region .

59. (Previously Presented) The implant of claim 38, wherein said single wire element consists of said U-shaped bend and said opposite legs extending therefrom.

60. (Currently Amended) The implant of claim 59, wherein said legs of said second portions are shaped to bear internally against and provide support for an articular surface of the bone fragment.

61. (Previously Presented) The implant of claim 38, wherein said bends which join said first and second portions are curved.

62. (Cancelled)

63. (Currently Amended) The implant of claim 38, wherein distal ends of the second portion of the legs of the wire element are shaped and arranged to be adapted to enter respective holes drilled in the unstable bone fragment.

64. (Currently Amended) The implant of claim 63, wherein ~~the distal end of~~ one of said legs of said second portion is longer than the ~~distal end~~ other of ~~the other of~~ said legs of the second portion to enable the distal ends of said legs are tips of said legs enter said drilled holes one after the other.

65. (Cancelled)

66. (Currently Amended) The implant of claim 38, wherein the ~~bent ends of~~ the legs of the second portion are inclined distally with respect to the vertical.

67. (Currently Amended) The implant of claim ~~66~~ 38, wherein ~~said bent ends of~~ said legs of said second portion are dimensioned ~~have sufficient length~~ to be adapted to penetrate into the ~~stable~~ unstable bone fragment.

68. (New) The implant of claim 38, wherein said bends of said legs extend out of the plane of the U-shaped bend in the form of loops that connect with said second portions, said second portions extending from said loops as straight lengths of said wire element.

69. (New) The implant of claim 68, wherein said second portions have straight lengths adapted to be substantially equal to the thickness of the bone fragment.

Claim Status

The Examiner has rejected Claims 38-45 and 58-67 on the combination of Medoff (US 5,709,682) hereafter Medoff in view of Petersen (US 3,826,024) hereafter Petersen.

Claim Amendments

Amendatory action has been taken in the claims to cancel and amend the claims so that only a single independent claim, i.e. Claim 38 remains in the application. All other claims are directly or indirectly dependent from Claim 38. Specifically, the claims now stand cancelled in the application are Claims 2, 3, 6-27, 34, 46-53, 55, 57, 62, 63 and 64. Dependent Claims 68 and 69 have been added.

REMARKS

Careful consideration has been given to the Official Action of August 19, 2010 and reconsideration of the application as amended is respectfully requested.

Amendatory action has been taken in the claims so that only independent claim 38 remains in the application. All other claims are dependent directly or indirectly from Claim 38 and therefore it is respectfully submitted that all claims in the application are now drawn to the elected invention and are entitled to examination on the merits. Claims 68 and 69 have been added to the application. Claim 68 is drawn to the configuration shown in Fig. 3 wherein the bend which joins the first and second portions extends out of the plane of the U-shaped bend. The bend is in the form of a loop of the wire and joins the first portion which lies in the plane of U-shaped bend and the second portion which lies outside the plane of the U-shaped bend, the second portion being straight and extending directly from the bend. Claim 69 is dependent from Claim 68 and is directed to the feature that the straight portions are of a length which is substantially equal to the thickness of the bone as shown in Figs. 2 and 7.

As seen by the Examiner, Medoff discloses a single wire buttress pin and fundamentally this patent is distinguished from the present invention in that the legs of the buttress pin extend parallel to one another throughout their length. The Examiner reads the pointed projections 41 as corresponding to the second portion of the buttress pin of the invention. These pointed projections which are intended to pierce a bone fragment are not structurally the same nor functionally equivalent to the straight portions which are of a length to bear against and buttress the bone fragment in the particular embodiment of claim 68. These straight portions extend within the bone over the length of the bone (as expressed in Claim 69) and provide a buttressing of the entire bone fragment. The Examiner has not found any equivalents in the Medoff patent regarding the formation of drilled holes in the bone fragment into which the second portions extend. Furthermore, the Examiner has not found any response in Medoff to the inequality of the legs of the second portion which enable the longer leg to be inserted first into the respective drilled hole after which the second straight portion is inserted into its respective drilled hole. As further noted with respect to Claim 68, the bends

which join the first and second portions extend as loops out of the plane of the first portion and are connected to the second portion to facilitate their engagement with the bone fragment. In Medoff, the pointed projections extend from a straight extension of the legs of the buttress pin at the lower surface thereof which is a completely different configuration and which cannot accomplish the function of the buttressing by the second portion over its entire length. Additionally absent in Medoff is the requirement that the length of the legs measured from the U-shaped bend are unequal. This permits the legs to buttress bone fragments that have irregular and non-orthogonal surfaces as explained in the specification.

The Examiner cites Petersen for showing a retainer pin which the Examiner considers, to one skilled in the art, to incorporate the various distances between the legs of the retainer of Petersen with the device of Medoff to have predictively achieved the result of facilitating the implantation of the Medoff device. The rejection is respectfully traversed as the Petersen patent provides no substantive support for making it obvious to combine this reference with Medoff to arrive at the claimed invention.

Specifically, Petersen is directed to a trenching machine which is adapted for cutting slots in the earth for the purpose of installation of drainage pipes in the cut slots. Basically, it is not considered obvious to one skilled in the art to use such a patent and consider it obvious for combination with a buttressing pin adapted to achieve fixation of a fractured bone fragment. It is respectfully submitted that Petersen is directed to non-analogous and non-pertinent art and it would not be obvious to one skilled in the art to combine Petersen with Medoff.

Specifically, the trenching machine of Petersen shows a chain carrying a plurality of cutting teeth which are respectively secured in holders and which serve to cut the trench in the earth. More specifically, each tooth 32 is supported in a holder 31 and a spool portion 51 of tooth 32 is retained in an opening 57 by a retainer 66. The Examiner refers to Fig. 9 for showing two unequally spaced portions of retainer 66. The Examiner regards these as justification for combination with Medoff in order to establish two unequally spaced portions of the legs of the buttress pin of Medoff. However, the retainer of Petersen is of

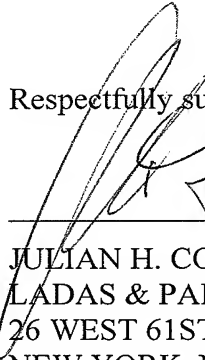
completely different construction and configuration and carries out a completely different result. Specifically, the retainer 66 is made of spring stock (col 4 lines 54-56). Initially, the legs 74a,b of the retainer 66 diverge outwardly (col 4 lines 62-63) and leg 74b is longer than leg 74a. Specifically, it is to be noted that initially the legs are not parallel to one another but are flared outwardly. In order to install the resilient retainer into an operative position, the longer leg is first inserted between the wall portion 61 and the shorter leg is then forced toward the longer leg until the legs fit between the walls 61. This involves a squeezing of the legs from their initial divergent position to the installed position where they are parallel to one another. In the assembled position of the retainer 66 in the holder 31 upper leg portions 68 fit around spool 51 and forwardly of shoulder 52 and thus prevent the withdrawal of the tooth from the holder, (col 4, line 63 to col 5, line 4). In order to free the tooth 32 to enable its withdrawal, the retainer is displaced downwardly and the outwardly offset leg portions 69 engage shoulders 63. Shoulder 52 is now free to move forwardly so that the tooth may be removed. Hence, the retainer 66 relies upon its elasticity and its displacement in order free the shoulder of the tooth in the retracted position and to engage the other pair of legs in the operative position under stress. Accordingly, the configuration of the retainer and its function are entirely dissimilar from that of the invention and it is not seen that one skilled in the art would find it obvious to apply the teachings of Petersen to Medoff in order to achieve a different function in a different way using a different configuration. In this regard, Medoff and the present invention rely on developing buttress forces along the length of the legs to prop or support the bone fragment under pressure for fracture fixation whereas Petersen develops laterally acting spring forces that apply no thrust forces along the legs but only squeezing forces to retain the tooth in place.

In the recent Supreme Court decision in the KSR case an Examiner was not given free authority to arbitrarily combine different features from different references in different fields of art in order to arrive at a claimed invention. On the contrary, the Court retained the prevailing conditions in the John Deere case, and herein there must be some rationality which will enable one skilled in the art to combine references to arrive at a justifiable rejection. In the present invention, the buttress pin serves as a means to prop or stabilize a fracture in order for its fixation. The cited Medoff patent also has a similar

objective. However, Petersen has no attributes which would remotely relate to such a purpose and its configuration is intended to provide two separate positions in which a tooth is locked or unlocked so that it can be retained or removed. Accordingly, the initially flared position of the legs of the retainer of Petersen and its need for being constructed of spring stock in order to be brought between initial and inoperative positions disqualify it as a valid reference upon which to ground a rejection based on the combination of Medoff and Petersen. In supporting the rejection of the claims on the combination of Medoff and Petersen the Examiner contends that the combination would have predictably achieved the result of facilitating the implantation of the Medoff device (column 5, lines 6-7). In point of fact this would not achieve the result and the objective of the invention is to buttress the bone fragment dependentl on the mounting of the legs to the stable bone fragment.

It is therefore respectfully submitted that the claims as now presented are not subject to rejection under the combination of Medoff and Petersen and favorable reconsideration is earnestly solicited.

Respectfully submitted,


JULIAN H. COHEN
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG.NO. 20302 TEL.NO. (212) 708-1900

Handwritten notes: Reg No 30026, For Julian H.

Handwritten signature: [Signature]